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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/417,251	10/13/1999	REBECCA E. CAHOON	BB1085-US-NA	7181

23906 7590 04/19/2002

E I DU PONT DE NEMOURS AND COMPANY  
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4417 LANCASTER PIKE  
WILMINGTON, DE 19805

EXAMINER

ZARA, JANE J

ART UNIT	PAPER NUMBER
1635	16

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

	Application No.	Applicant(s)
	09/417,251	CAHOON ET AL.
	Examiner Jane Zara	Art Unit 1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 16-18,22-30 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 16-18,22-30 and 36-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All .b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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## **DETAILED ACTION**

This Office action is in response to the communication filed September 27, 2001 and March 5, 2002, Paper Nos. 11 and 14.

Claims 16-20, 22-30 and 36-38 are pending in the instant application.

Applicants' request for reconsideration of the finality of the rejections of the last Office action is persuasive, and, therefore, the finality of that action is withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments and Amendments***

#### **Withdrawn Rejections**

Rejection of claims 19, 20 and 35 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, is withdrawn in light of Applicant's amendments filed March 5, 2002, Paper No. 14.

#### **Maintained Rejections**

Claims 16-18, 22-30 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, for the reasons set forth in the Office action mailed June 29, 2001, Paper No. 10.

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Applicant's arguments filed March 5, 2002 have been fully considered but they are not persuasive. Applicants assert that adequate written description has been provided because the claimed compounds share homology with previously identified disulfide isomerases and furthermore that the claimed compound contains two conserved active site domains, as well as an endoplasmic reticulum retaining signal. Contrary to Applicants' assertions, sequence alignments with previously identified polynucleotides or polypeptides and the identification of pentapeptide sequences known to be conserved active site domains within a purported translation product, derived from a polynucleotide sequence, does not provide adequate written description for the genus comprising any polypeptides which share at least 85% identity with SEQ ID NO: 10.

Claims 16-20, 22-30 and 36-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the Office action mailed June 29, 2001, Paper No. 10.

Applicant's arguments filed March 5, 2002 have been fully considered but they are not persuasive. Applicants argue that the claims are enabled because the instant disclosure provides a polynucleotide sequence (Seq ID No: 9), and its predicted translation product (Seq ID No: 10), as well as describing an assay for determining disulfide isomerase activity. Contrary to Applicants' assertions, a citation of an assay which exists for measuring enzyme activity, coupled

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with the identification of active site domains within a predicted translation product, do not provide enablement for the claimed invention. No activity data has been provided for the claimed compounds. Contrary to Applicants' assertions, it would require undue experimentation beyond that provided in the instant specification to identify and describe the members of the genus claimed, which includes any homologues sharing at least 85% identity with SEQ ID NO: 10, and which contain disulfide isomerase activity.

New Rejections

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-20, 22-30 and 36-38 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification as filed does not disclose or provide any evidence for the function of the claimed polynucleotide sequence of SEQ ID NO: 9, or of its predicted translation product comprising SEQ ID NO: 10, or its homologues comprising at least 85% identity with SEQ ID NO: 10, such that another non-asserted specific and substantial credible utility would be well established. Additionally, there is no art of record that discloses or provides sufficient evidence that discloses the function of the predicted amino acid sequence of SEQ ID NO: 10 or the

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claimed homologues thereof, such that another non-asserted specific and substantial credible utility would be well established. With regard to the asserted use of the claimed predicted translation product(s), the function of the polypeptide or any homologues thereof is not specifically known and the mere assertion that they are protein disulfide isomerases because they share sequence homology with other disulfide isomerases would not be accepted by one skilled in the art as being reasonable or credible in view of the contemporary knowledge in the art. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981{1996}]; Wells et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)]. Homology does not imply function. Since there is no evidence on the record for the

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function of the purported amino acid sequence of SEQ ID NO: 10, its homologues, the asserted utility is inoperative and is therefore not credible.

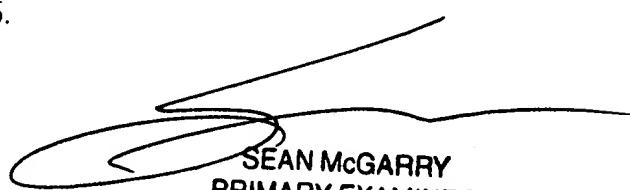
### ***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

April 11, 2002

  
**SEAN McGARRY**  
PRIMARY EXAMINER  
AU 1635